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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,867	05/14/2001	Joan H. M. Knoll	30307-A	9935

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HOVEY WILLIAMS, LLP
Suite 400
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Kansas City, MO 64108

EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/854,867

Applicant(s)

KNOLL ET AL.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group IV, claims 44 and 45 in the reply filed on May 25, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 44 and 45 are pending. Nonelected claims 1-43 have been cancelled.

Objection to the Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see, for example, page 24, 37 and 38). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
4. New corrected drawings are required in this application. This application appears to contain black/white drawings of Figures 1-12, 15 and 16. These figures are described on pages 6 and 7 of the specification. However, the drawings are essentially too dark to determine whether the drawings contain the information set forth in the specification. It is noted that Figures 1-12 were also presented in parent application 09/573,080. However, the drawings in the '080 application were presented in color format. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S.

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Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

5. The specification at page 51 state that "the subject matter of Disclosure Document #471449 filed March 27, 2000, is also incorporated by reference herein." As stated in the MPEP 1706, "The Disclosure Document will be preserved by the USPTO for two years after its receipt. It will then be destroyed unless it is referred to in a separate letter in a related patent application filed within the two-year period." However, the present application was not accompanied by a separate letter, filed within two years of the March 27, 2000 filing, referring to the Disclosure Document by its title, number and date of receipt in the USPTO. Accordingly, it is not proper to refer to this disclosure document or to incorporate by reference this disclosure document, since this document has not been retained by the USPTO.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a written description rejection.

The claims are drawn to methods for determining a chromosome breakpoint comprising the steps of providing a pair of labeled single copy probes that hybridize to opposite sides of the breakpoint, reacting the pair of probes with a target sequence and detecting hybridization of the probes to the target sequence.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed”. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision.

In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA...’requires a precise definition, such as by structure, formula, chemical name, or physical properties’, not a mere wish or plan for obtaining the claimed chemical invention”.

In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, the specification discloses repeat sequences consisting of the sequences of SEQ ID NO: 1-428 and 447-479 (see page 25 and Table 1). The specification also teaches that sequences which do not contain a repeat were isolated using the primers of SEQ ID NO: 429-446 (see Table 2). The specification teaches that probes obtained from amplification reactions using these primers were then used in hybridization methods. Figure 6 illustrates hybridization using the probes of 5170, 3691, 3344 and 2848 that were designed to hybridize with the HIRA gene. At page 33, the specification states that "In the Fig. 6 photograph, the probe was hybridized to a single region of both chromosome 22s in a normal individual." The specification (Example 2) also teaches the development of probes to NECDIN and CDC2L1 genes. The nucleic acids set forth in the specification which are considered to be single copy probes and are said to be free of repeat sequences constitute 4 probes for the HIRA gene, 2 probes for the CDC2L1 gene and 2 probes for the NECDIN gene. On pages 37-38, it is stated that a "number of probes specific to additional genetic disorders and cytogenetic abnormalities were developed and are set forth in the accompanying CD-R." However, the claims are drawn to methods which require the use of probes that hybridize to opposite sides of a breakpoint. The HIRA, CDC2L1 and NECDIN probes are not characterized as hybridizing to either side of a breakpoint region. The specification does disclose additional probes in Table 4. This table

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includes 11 probes for the 9;22 (q34;q11.2) translocation involving the ABL1 and BCR genes. Of the 11 probes, 2 of the probes are characterized as cross-hybridizing to interspersed repetitive sequences and thereby are not considered to be "single-copy probes." The specification (page 46) teaches that "For ABL1, two of the probes are predicted to be proximal of the breakpoint (SEQ ID Nos. 516/517 and 518/519), and the others are distal to the breakpoint (SEQ ID Nos. 520 through 531)...It will be evident to one skilled in the art that the region of breakage can be more precisely refined by hybridizing probes from the single copy intervals between Seq ID Nos. 519 and 520. The exact location at the breakpoint can be then determined from the genomic sequences of the refined breakage region." It is noted that the present claims require use of the probes for "ascertaining the location of said breakpoint." The specification does not clearly define what is intended to be encompassed by the location. However, the teachings in the specification and prior art indicate that the location of a breakpoint includes defining the location in terms of the sequences immediately adjacent to the breakpoint. It does not appear that the present probes actually serve the function of being useful for determining the location of the breakpoint within this definition of what constitutes the location of the breakpoint. Rather, the disclosed probes appear to be useful for designing additional probes which can then be used to determine the specific location of the breakpoint and/or to identify a region of genomic DNA involved in a breakpoint and/or to generally detect a breakpoint. Additionally, Table 4 discloses one probe to the AML1 gene and 3 probes to the TEL/ETV6 gene wherein the probes are useful for detecting

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the t(12;21)(p13.2;q22.1) translocation. A number of additional probes are also disclosed which are characterized as being useful detecting deletions or inversions. However, the specification does not appear to teach that these probes hybridize to opposite sides of a breakpoint and can be used to determine the location of a breakpoint. Further, the specification (page 50) states that "hybridization of presumed single copy probes to interspersed repetitive sequence families was detected, despite the fact that these probes were filtered for repetitive sequences using RepeatMasker software. One probe, mapping to chromosome 17p11.2, within the interval commonly deleted in Smith-Magenis syndrome (amplified with SEQ ID No. 586/587), was found to cross-hybridize with interspersed repeats." This teaching indicates that absence of the sequences of SEQ ID NO: 1-428 and 447-479 alone does not allow one to conclude that a probe is a "single copy nucleic acid probe" since additional repeat sequence exist throughout the genome. Thereby, the specification exemplifies a limited number of probes which hybridize to opposite sides of a breakpoint and which can be used to determine the location of the breakpoint. However, the genus of probes which would hybridize adjacent to known or unknown breakpoint sites is significantly large. The specific probes disclosed in the specification do not constitute a representative number of probes within the broadly claimed genus of probes. Additionally, the present claims do not recite any specific structural limitations, such as the nucleotide sequence of the claimed hybridization probes.

It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, biological activity of an encoded protein product, etc.). In the instant case, the claims do not sufficiently define the probes in terms of any other identifying characteristics. The claims define the probes in terms of what they are not, but do not clearly define the probes in terms of what they are. Such a definition allows one to know when a probe does not meet the claim limitations, but does not allow one to fairly determine when a probe does in fact meet the claim limitations. While the claims recite that the probes are single copy nucleic acid probes and thereby are probes which do not hybridize to repetitive sequences, the specification and claims do not clearly characterize the genus of all repetitive sequences. The specification teaches repeat sequences consisting of the sequences of SEQ ID NO: 1-428 and 447-479 (see page 25 and Table). However, additional repeat sequences exist beyond those listed in SEQ ID NO: 1-428 and 447-479. Additionally, the phrase "repeat sequence" has not been clearly defined in the specification. It is unclear as to whether a repeat sequence is intended to include or exclude triplet repeats which are found throughout the genome, e.g. "CAG" repeat sequences. It is also unclear as to whether repeat sequences are intended to include or exclude promoter, enhancer and other types of regulatory sequences that are found throughout the genome. Thereby, defining the probes as being a single copy probes does not provide a sufficient meaningful characterization of the probes. The claims further recite that the probes are of a "predetermined sequence." However, the claims do not set forth

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what constitutes the "predetermined sequence." Accordingly, the known repeat sequences required to practice the claimed methods have not been sufficiently defined in terms of their structure and the known sequences required to define the claimed probes have not been adequately defined in terms of their structure. Further, Applicants have not provided sufficient evidence to show that they were in possession, at the time of filing, of a representative number of the claimed nucleic acid hybridization probes. Therefore, the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

7. Claims 44 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 44 and 45 are indefinite over the recitation "single copy nucleic acid probes" because it is not clear as to what is intended to be encompassed by such probes. The specification at page 9 states that "single copy" refers to a "sequence which is strictly unique (i.e., which is complementary to one and one only sequence in the corresponding genome) but also covers duplicons and triplicons. Stated otherwise, a "single copy" probe in preferred forms will hybridize to three or less locations in the genome." It is further stated that "single copy" or "unique" DNA sequences "are essentially free of sequences complementary to repeat sequences within the genome of which the target is a part. Accordingly, a

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probe made up of a single copy or unique sequence is complementary to essentially only one sequence in the corresponding genome" (see page 8 of the specification). These teachings in the specification do not provide a clear and definite meaning for the phrase "single copy nucleic acid probe." It is unclear as to what constitutes "essentially free" and "complementary to essentially one sequence." The definitions do not clarify when it is acceptable for the "single copy probe" to hybridize to more than one sequence and it is unclear as to what conditions of hybridization are utilized to determine whether the probe hybridizes to a single or multiple sequences. The definition does not clarify the degree of complementarity that is shared between the probe and the target sequence and thereby it is unclear as to whether the probe is fully complementary to the one or more target sequences or may share some unstated level of complementarity with the one or more target sequences. It is also unclear as to whether it is acceptable for the "single copy probe" to hybridize to variants of the a sequence, amplified sequences that are not "duplicons" or "triplicons" or pseudogene sequences.

Additionally, the sequences that are translocated to generate a breakpoint generally arise from other locations within the genome. Consequently, the sequences on either side of the breakpoint may also be present at another location in the genome (i.e., at the wildtype allele vs at the translocated allele). It is unclear as to whether a single copy probe hybridizes to both the wildtype sequence and the translocated sequence. If the probe hybridizes to only the translocated sequences, then it would appear that the probe should also contain

sequences that are generated by the translocation event. However, the claims require the use of probes that hybridize to opposite sides of the breakpoint. The claims do not require single copy probes that hybridize to the breakpoint itself.

Further, the single copy probe is defined in terms of the fact that it is essentially free of "repeat sequences." However, it is unclear as to what is intended to be meant by "repeat sequences." The specification at page 9 provides a definition of what may be included by a repeat sequence. The specification states that "Generally speaking, a repeat sequence appears at least about 10 times in the genome... and has a length of at least about 50 nucleotides. " However, these examples of what may be included by a repeat sequence do not provide a clear and fixed definition for what constitutes the complete genus of a repeat sequence. The specification further states that repeat sequences repeated appear in the genome and have at least about 60% identity with other repeats. However, the specification does not clearly define the repeats in terms of the number of times they must appear in the genome in order to constitute a repeat. The repeat sequences are also not adequately defined in terms of their length. It is also unclear as to what constitutes a repeat sequence since the repeat sequences are defined in terms of having only about 60% identity with other repeat sequences, yet the other repeat sequences have not been clearly defined. Therefore, it is unclear as to whether a repeat sequence would include sequences such as triplet repeats that are present throughout the genome, e.g. "CAG" triple repeats, and as to whether repeat sequences include short regulatory sequences, such as TATA and CAAT boxes, which are also

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present throughout the genome. For these reasons, it is unclear as to what would be the sequence, length and frequency of occurrence of a "single copy nucleic acid probe" and thereby one of skill in the art could not determine the meets and bounds of the claimed invention.

B. Claims 44 and 45 are indefinite. The claims are drawn to a method for determining a chromosome breakpoint. However, the claims recite the final step of detecting hybridized probes "as a way of ascertaining the location of said breakpoint." Accordingly, it is not clear as to whether the claims are intended to be limited to methods for determining or detecting a breakpoint or to methods for determining the location of a breakpoint. If the methods are intended to be limited to ones which determine the location of the breakpoint, it is unclear as to how the single step of detecting the hybridized probes results in the determination of the location of a breakpoint.

C. Claim 45 is indefinite because it is unclear as to whether the step recited in claim 45 is performed in addition to the steps set forth in claim 44 (i.e., 2 sets of probes are utilized) or whether the step recited in claim 45 is intended to further characterize the steps set forth in claim 44. In the later case, it is unclear as to how claim 45 further defines the probes or method steps of claim 44. Claim 44 requires the use of a pair of labeled probes that hybridize on opposite sides of the breakpoint, while claim 45 requires the use of a plurality of labeled probes that hybridize to one side of a breakpoint and a plurality of labeled probes that hybridize to the other side of a breakpoint. If the recited method is intended to include only a single step of providing and reacting the probes with the target

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sequence, then claim 45 would not be further limiting from claim 44 since claim 44 requires the use of a pair of probes and claim 45 requires the use of a plurality probes for each side of the breakpoint. It is also unclear as to whether the claim intends to refer to a mixture of probes each distinct from one another or a mixture containing multiple copies of the same probe. The claims should be amended to clarify the relationship between the probes and the method steps of claims 44 and 45.

Priority

8. It is noted that claims 44 and 45 are entitled to priority only to the present filing date of May 14, 2001. Parent U.S. Application 09/573,080 teaches that "One application of the use of multiple fragment probes is in the detection of translocations involving two different chromosomes. Proportionately increasing the complexity of the probe also permits analysis of multiple compact regions of the genome simultaneously. The portion of the probe targeted to one side of the break point can be labeled differently from that targeted to the other side of the break point so that the fused translocated chromosome is detected by both labels and is distinguishable from the intact chromosome." However, these teachings do not provide support of the broader concept set forth in the present claims of determining any chromosome breakpoint (i.e., including breakpoints other than translocations) by contacting chromosomal target sequences with probes that hybridize to opposite sides of the breakpoint and detecting hybridization "as a way of ascertaining the location of said breakpoint."

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 44 and 45 are rejected under 35 U.S.C. 102(e) and 102(a) as being anticipated by Rowley et al (U.S. Patent No. 6,121,419).

Rowley et al teach a method for determining a chromosome breakpoint wherein the method comprises contacting chromosomal DNA with a pair of probes wherein one probe hybridizes telomeric to the breakpoint and the other probe hybridizes centromeric to the breakpoint and detecting hybridization of the probes to chromosomal DNA as a way of determining the presence and/or location of the breakpoint (see, for example, column 6). In particular, Rowley teaches methods which detect MLL chromosomal aberrations, wherein the aberrations specifically involve fusion of chromosomal band 11q23 with chromosomal bands 4q21, 6q27, 9p22, and 19p13.3 (see abstract). Rowley (column 6) states that "Cloned DNA probes from both sides of the translocation breakpoint region can be used with FISH to detect the translocation in leukemic

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cells. In normal cells, these two probes would be together and they would appear as a single signal. In cells with a translocation, the centromeric probe would remain on the derivative 11 chromosome whereas the telomeric probe would be translated to the other derivative chromosome. This would result in two smaller signals, one on each translocation partner." Rowley further teaches use of the centromeric probe 1.5EB and the telomeric probes 0.3BE, 14-7 and 0.8E in FISH and Southern hybridization methods (column 6). The probes of Rowley are considered to be "single copy nucleic acid probes" because the probes are characterized as being MLL specific and the probes do not cross-hybridize with non-MLL sequences. With respect to claim 45, the method of Rowley is considered to be one which provides a plurality of labeled single copy probes since the method of FISH requires the use of a solution containing many copies of the individual probes.

10. Claims 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanaka et al (Cancer Genetics and Cytogenetics. 1999. 113: 29-35).

Tanaka et al teach a method for determining a chromosome breakpoint wherein the method comprises contacting chromosomal DNA with a pair of probes wherein one probe hybridizes telomeric to the breakpoint and the other probe hybridizes centromeric to the breakpoint and detecting hybridization of the probes to chromosomal DNA as a way of determining the presence and/or location of the breakpoint (see, for example, page 30). In the method of Tanaka, sets of fluorescently labeled probes are used to detect the AML (8;21)(q22;q22)

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translocation. In particular, Tanaka teachings performing FISH using the cY107 and cYR4 probes which hybridize to sequences 5' and 3' of the AML breakpoint, respectively. The probes of Tanaka are considered to be "single copy nucleic acid probes" because the probes are characterized as being AML-specific and the probes do not cross-hybridize with non-AML sequences (pages 30-31). With respect to claim 45, the method of Tanaka is considered to be one which provides a plurality of labeled single copy probes since the method of FISH requires the use of a solution containing many copies of the individual probes.

11. The related art made of record and not relied upon is considered pertinent to applicant's disclosure.

Palanisamy (US 2002/0192692, filed 5/14/02; provisional filing date 5/14/01) discloses methods for detecting a translocation using probes which hybridize to each side of a breakpoint wherein the probes are free of repeat sequences.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

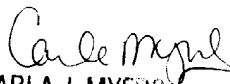
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Carla Myers
August 2, 2004


CARLA J. MYERS
PRIMARY EXAMINER